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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4500
FAX: 504-253-4566

December 9, 1999

**WARNING LETTER 2000-NOL-09**

***FEDERAL EXPRESS***
**OVERNIGHT DELIVERY**

John E. Eschete, Owner
Eschete's Seafood, Inc.
229 New Orleans Boulevard
Houma, Louisiana 70364-3345

Dear Mr. Eschete:

On March 23-25, 1999, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your seafood dinner processing plant, located at 229 New Orleans Boulevard, Houma, Louisiana. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, *Code of Federal Regulations*, Part 123 and the Current Good Manufacturing Practice (CGMP) regulations for foods, Part 110. This causes your finished products, various seafood entrees, to be adulterated within the meaning of 402(a)(4) of the Federal Food, Drug and Cosmetic Act.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the March 23-25, 1999, inspection, the FDA investigator observed shortcomings in your system that were directly related to those pointed out in the July 8-9, 1998, inspection, and stated in the untitled letter sent to your firm on July 27, 1998. The FDA investigator also provided your firm with a copy of the Domestic Seafood HACCP Report (Form FDA-3501) and the Form FDA-483, which presents his evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. The Form FDA-483 is enclosed for your review. The observations of concern to us are as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with Title 21, CFR, Part 123.6(b). However, your firm does not have a HACCP plan to control the food safety hazards of undeclared sulfites for frozen stuffed shrimp.

  We noted in the July 1998 inspection that raw frozen shrimp with sodium bisulfate was received. Your labels for the shrimp products declared, "sodium bisulfite." In addition to providing for the control of sulfites in a plan for frozen stuffed shrimp, you should have all your labels corrected to read, "sodium bisulfite" or the specific name of the actual sulfiting agent that is used.

  Since you chose to include corrective actions in your HACCP plan, your described corrective action must be appropriate, in order to comply with Title 21, CFR, Part 123.7(b). However, your corrective action plan for "heat and serve" products, and soups and sauces at the labeling critical control points to control sulfiting agents does not prevent adulterated product or products that are injurious to health from entering commerce.

- You failed to adequately monitor sanitation from March 23-25, 1999, in that the firm is not monitoring for the prevention of cross contamination, maintenance of hand washing and hand sanitizing, protection from adulterants, as required by Title 21, CFR, Part 123.11(b).

Objectionable equipment and insanitary conditions as listed on Form FDA-483 and Form FDA-3501 are an indication that sanitation monitoring [Title 21, CFR, Part 123.11(b)] at the firm is inadequate. An effective HACCP system is built upon implementing acceptable sanitation standard operating procedures. The noted objectionable insanitary conditions include the following:

- Employees were noted to wear hand jewelry and earrings while handling claw crabmeat and shrimp fettuccini; and,

- Employees were observed touching insanitary items such as eyeglasses, doors, cabinet handles and door handles then handling the product without first washing and sanitizing their hands.

As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

Your should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be

completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Patricia K. Schafer, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Schafer (504) 253-4500.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483